REMARKS

Status of the claims

Claims 1-15 were pending as originally filed.

Claim 1 has been amended as shown above to incorporate the limitations of original claim 11. Accordingly, claim 11 has been canceled, without prejudice or disclaimer. New claims 16 to 27 have been added and find support, for example, in paragraphs [0035] to [0038] and Figs. 2A-2D. Thus, claims 1-10 and 12-27 are pending as shown above.

35 U.S.C. § 102(b)

Claims 1-10 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO 01/05873 (hereinafter "Zalipsky"). (Office Action, pages 2-3).

Claim 1 has been amended to incorporate the limitations of previous claim 11. The Examiner has acknowledged that Zalipsky does not disclose liposomes as claimed with an entrapped chemotherapeutic agent. (Office Action, page 4). Accordingly, this reference does not anticipate claim 1 as pending the rejection may be withdrawn.

With regard to new claims 16-27, Applicants note that the liposome structures encompassed by the claims exclude the structure disclosed in Zalipsky. Accordingly, new claims 16-27 are also not anticipated by this reference.

35 U.S.C. § 103(a)

Claims 1-13 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Zalipsky in view of U.S. Patent No. 5,786,387 (hereinafter "Watanabe"). (Office Action, pages 4-5). Zalipsky was for disclosing liposomes containing PEG-substituted neutral polymers and for "inherently" teaching reduction in complement activation. *Id.* Watanabe was cited for teaching a lipid double chain derivative containing a polyoxyethylene that can be incorporated into a liposome and used to carry anticancer drugs. *Id.* In addition, claims 1-15 were rejected as allegedly obvious over Zalipsky in view of Watanabe and in further view of U.S. Patent No. 5,945,122 (hereinafter "Abra"). (Office Action, pages 5 to 7). Zalipsky and Watanabe were cited as above and Abra was

cited for teaching a liposome composition with an entrapped cisplatin. (Office Action, page 6).

(a) Alleged inherency cannot be the basis of an obviousness rejection

Because alleged inherency cannot form the basis of an obviousness rejection, Applicants traverse.

The pending claims are directed to methods of reducing liposome-induced complement-activation. As acknowledged, all of the cited references are silent as to complement activation by the particularly claimed molecules. It is axiomatic that an allegedly "inherent" use, if not known at the time of the invention, cannot form the basis for rejecting the claimed invention as obvious under section 103. *See, e.g., In re Shetty*, 195 USPQ 753 (CCPA 1977). The applicant in *In re Shetty* claimed a composition of certain adamantane compounds and a method of using them to curb appetite in animals. Although the cited reference taught structurally similar compounds at similar dosages, the court reversed the PTO finding of obviousness with regard to the method claims because nothing in the reference suggested using the structurally similar compounds to curb appetite. The court, quoting from *In re Spormann,* 363 F.2d 444 (CCPA 1966), stated that

> "[t]he inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Shetty, supra* quoting *In re Sporman,* 150 USPQ 449 (CCPA 1966).

See, also, *in re Naylor,* 369 F.2d 765, 768 (CCPA 1966)

> "[Inherency] is quite immaterial if ... one or ordinary skill in the art would not appreciate or recognize the inherent result.

Clearly then, as the skilled artisan would not have recognized or appreciated the effect particular liposomes would have on complement activation, an obviousness rejection of pending claims 1-10 and 12-15 based on allegedly inherency is improper. Indeed, as clearly indicated in Table 5 of the as-filed specification, not all liposomes or micelles induce complement activation. Thus, not all will necessarily reduce complement activation as claimed. On this basis alone, the rejection should be withdrawn.

(b) The references do not teach all the limitations of the claimed subject matter

As acknowledged, Zalipsky does not teach or suggest the particular lipopolymers as set forth in claims 16-27 and does not teach their use to reduce complement activation (claims 1-10, 12-15). Functional language, such as reducing complement activation, must be considered in determining the scope of the claims and applying the references. See, MPEP § 2173.05(g). Here, when the claim is properly considered as a whole, including functional language, it is clear that Zalipsky does not teach or suggest reducing complement activation with a liposome comprising a chemotherapeutic agent (claims 1-10, 12-15) or with a liposome of the structure set forth in new claims 16-27.

As with Zalipsky, the Office has admitted that the secondary references (Watanabe and Abra) fail to teach all the elements of the claims, including (as with Zalipsky) reducing complement activation. Furthermore, as noted above and shown for example in Table 5 of the as-filed specification, not all liposomes or micelles induce complement activation. Since functional language must be considered and the recited functional language of reducing complement activation is lacking from all the cited references, a prima facie case of obviousness cannot be established.

For all of the aforementioned reasons, the rejection of claims 33-36 under 35 U.S.C. § 103(a) should be withdrawn.

CONCLUSION

In light of the amendments and remarks presented in this paper, it is believed that the claims are in condition for allowance.

Please direct all communications to the undersigned, using the contact information provided below.

Respectfully submitted,

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